



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

09/NOV/2020

MEMORANDUM

Subject: Name of Pesticide Product: Aceto Etoxazole Technical
EPA Reg. No./File Symbol: 33427-RE
DP Barcode: D458528
Decision No: 559096
Action Code: R334
PC Code: 107091 (etoxazole)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Marianne Lewis, Risk Management Team 01
IVB 3
Registration Division (7505P)

Applicant: Aceto US, LLC
c/o Product & Regulatory Associates, LLC

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Ettoxazole	99.36
<u>Other ingredients:</u>	<u>0.64</u>
Total:	100.00

ACTION REQUESTED: The Risk Manager requests review of acute toxicity studies submitted for EPA File Symbol 33427-RE.

BACKGROUND: Aceto US, LLC has submitted six acute toxicity studies with MRIDs 510084-05 to -10 to support the registration of the proposed product, Aceto Etoxazole Technical, EPA File Symbol 33427-RE. The submission includes a label, company letter and Basic CSF dated November 26, 2019.

GLP: Yes

DEVIATIONS: None

COMMENTS, FINDINGS AND RECOMMENDATIONS:

1. The six acute toxicity studies with MRIDs 510084-05 to -10 are acceptable to support the registration of 33427-RE.
2. The acute toxicity profile for the proposed product, Aceto Etoxazole Technical, EPA File Symbol 33427-RE, is as follows:

acute oral toxicity	IV	acceptable	MRID 51008405
acute dermal toxicity	IV	acceptable	MRID 51008406
acute inhalation toxicity	IV	acceptable	MRID 51008407
primary eye irritation	III	acceptable	MRID 51008408
primary skin irritation	IV	acceptable	MRID 51008409
dermal sensitization	negative	acceptable	MRID 51008410

3. The proposed Basic CSF must be accepted by the CITAB Product Chemistry Team.

PRECAUTIONARY LABELING: Based on the toxicity profile, the following are the precautionary and first aid statements for this product:

Product ID #: 33427-RE

Product Name: Aceto Etoxazole Technical

Signal Word: CAUTION

Hazards to Humans and Domestic Animals:

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. (Appropriate protective eyewear may be specified, if applicable.)

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

Note: The proposed label submitted for 33427-RE has first aid statements for all routes of exposure. These statements are acceptable.

DATA EVALUATION RECORD

Product Reg. No.: 33427-RE

Product: Aceto Etoxazole Technical

1. DP BARCODE: D458528				
2. PC CODE: 107091				
3. CURRENT DATE: November 9, 2020				
4. TEST MATERIAL: Etoxazole Technical AG35184 (Batch #s 20181107, 20181120 and 20181121; PSL Reference Numbers 190603-2H, 190603-3H and 190603-4H, respectively; PSL Reference Number 190603-4H was used for all studies except for acute inhalation which used 190603-2H; Etoxazole 97.44%; pH 6.43; off-white powder)				
Study/Species/Lab Study #/Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity Sprague-Dawley derived albino rat Product Safety Labs Study #50645 August 8, 2019 OCSP 870.1100; OECD 425	51008405	LD ₅₀ Females > 5000 mg/kg A total of three rats were tested at 5000 mg/kg. The test substance was administered as a 40% w/w mixture in corn oil. Preliminary sample preparation assessments conducted by PSL indicated that mixtures in excess of 40% were too viscous to be administered properly. Due to the high volume of test mixture to be administered (12.50 mL/kg), each animal's dose was divided into two approximately equal portions, administered two hours apart. One female was tested at the limit dose of 5000 mg/kg. The animal survived so two additional females were tested. They both survived. All animals survived and gained weight. No clinical signs of toxicity were observed. No gross abnormalities were noted at	IV	A

		necropsy.		
Acute dermal toxicity Sprague-Dawley derived albino rat Product Safety Labs Study #50646 July 29, 2019 OCSP 870.1200; OECD 402	51008406	LD ₅₀ > 5000 mg/kg (both sexes) A total of 5 male and 5 female rats were tested at 5000 mg/kg. The substance was applied as a dry paste (65% w/w mixture in distilled water). Preliminary sample preparation assessments conducted by PSL indicated that mixtures in excess of 65% were too dry to assure adequate skin contact. All animals survived and gained weight. No clinical signs of toxicity or dermal irritation were observed. No gross abnormalities were noted at necropsy.	IV	A
Acute inhalation toxicity Sprague-Dawley derived albino rat Product Safety Labs Study #50647 July 29, 2019 OCSP 870.1200; OECD 403	51008407	LC ₅₀ > 2.15 mg/L (both sexes) A total of 5 male and 5 female rats were tested. MMAD (µm): 3.19 µm GSD: 2.29 Nominal concentration 5.68 mg/L All animals survived and gained weight. Following exposure, one male exhibited ocular discharge on days 3-5; no other clinical signs of toxicity were observed. No gross abnormalities were observed at necropsy.	IV	A
Primary eye irritation New Zealand albino rabbit Product Safety Labs Study #50648	51008408	Three female rabbits were tested. The test substance was a powder and it was instilled as received.	III	A

July 31, 2019 OCSPP 870.2400; OECD 405		<p>One-tenth of a milliliter (0.071 grams) of the test substance was instilled into the right eye of each rabbit.</p> <p>Corneal opacity was observed in one eye at 24 hours only. No iritis was observed.</p> <p>Positive conjunctival chemosis was observed in one eye at one hour only. Scores of 1 (not a positive effect) were noted for redness, chemosis and/or discharge in all eyes from one to 48 hours. No positive scores were noted at 48 hours and all eyes were free of irritation at 72 hours.</p> <p>Severity of Irritation Mean Score = 6.0 at 1 hour.</p>		
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<p>Primary dermal irritation New Zealand albino rabbit Product Safety Labs Study #50649 July 31, 2019 OCSPP 870.2500; OECD 404</p>	<p>51008409</p>	<p>PDII = 0.4</p> <p>Three female New Zealand albino rabbits were tested.</p> <p>The substance was applied as a dry paste (65% w/w mixture in distilled water). Preliminary sample preparation assessments conducted by PSL indicated that mixtures in excess of 65% were too dry to assure adequate skin contact.</p> <p>Five-tenths of a gram of the test substance (0.77 g of the prepared test mixture) was placed on a 1-inch by 1-inch gauze pad and applied to one 6 cm² intact dose site on each animal.</p> <p>Very slight erythema was noted at all dose sites 30-60 minutes after patch removal. Two dose sites were free of irritation at 24 hours. All sites were free of edema and erythema by 72 hours.</p>	<p>IV</p>	<p>A</p>
<p>Dermal sensitization Hartley albino Guinea pig Buehler Product Safety Labs Study #50650 August 26, 2019 OCSPP 870.2600; OECD 406</p>	<p>51008410</p>	<p>Negative for sensitization</p> <p>34 male and female Guinea pigs were used in the study.</p> <p>A 65% w/w mixture of the test substance in a 2% w/v solution of carboxymethylcellulose in distilled water was used for the induction and the challenge. Preliminary sample preparation assessments conducted by PSL indicated that mixtures in excess of 65% were too dry to assure adequate skin contact.</p>	<p>--</p>	<p>A</p>

		Positive Control Study: Results of the historical positive control study conducted with HCA are acceptable.		
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**Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap
W = Waived**